

Please Direct All Correspondence to Customer Number **20995**

**TRANSMITTAL LETTER**  
**INFORMATION DISCLOSURE STATEMENT**

Applicant : Brauker, et al.  
App. No : 10/789,359  
Filed : February 26, 2004  
For : INTEGRATED DELIVERY DEVICE FOR  
CONTINUOUS GLUCOSE SENSOR  
Examiner : Mendez, Manuel A.  
Art Unit : 3763

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

October 6, 2005

(Date)

Rose M. Thiessen, Reg. No. 40,202

**Mail Stop Amendment**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement and PTO/SB/08 equivalent listing references for consideration:
  - (X) Listing 109 references.
  - (X) Enclosing 50 references.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

Rose M. Thiessen  
Registration No. 40,202  
Attorney of Record  
Customer No. 20,995  
(619) 235-8550



## INFORMATION DISCLOSURE STATEMENT

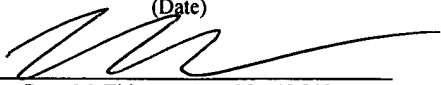
Applicant : Brauker, et al.  
App. No : 10/789,359  
Filed : February 26, 2004  
For : INTEGRATED DELIVERY DEVICE  
FOR CONTINUOUS GLUCOSE  
SENSOR  
Examiner : Mendez, Manuel A.  
Art Unit : 3763

## CERTIFICATE OF MAILING

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

October 6, 2005

(Date)

  
Rose M. Thiessen, Reg. No. 40,202

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 109 references to be considered by the Examiner. Also enclosed are 50 foreign patent references and/or non-patent literature as listed on the Information Disclosure Statement.

This Information Disclosure Statement is being filed before the receipt of a first Office Action on the merits, and presumably no fee is required. If a first Office Action on the merits was mailed before the mailing date of this Statement, the Commissioner is authorized to charge the fee set forth in 37 C.F.R. § 1.17(p) to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 10/6/05

By: 

Rose M. Thiessen  
Registration No. 40,202  
Attorney of Record  
Customer No. 20,995  
(619) 235-8550

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application No. 10/789,359  
 Filing Date February 26, 2004  
 First Named Inventor Brauker, et al.  
 Art Unit 3763  
 Examiner Mendez, Manuel A.  
 Attorney Docket No. DEXCOM.037A

SHEET 1 OF 5

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1.	2004-0015134A1	01/22/2004	Lavi, et al.	
	2.	2004-0068230A1	04/08/2004	Estes, et al.	
	3.	2005-01121669A1	05/26/2005	Brauker, et al. (DEXCOM.012A)	
	4.	2005-0043598	02/24/2005	Goode, et al. (DEXCOM.027A)	
	5.	2005-0090607 A1	04/28/2005	Tapsak, et al. (DEXCOM.028A)	
	6.	2005-0192557A1	09/01/2005	Brauker, et al. (DEXCOM.037A)	
	7.	2005-0031689A1	02/10/2005	Shults, et al. (DEXCOM.012CP1)	
	8.	2005-0033132	02/10/2005	Shults, et al. (DEXCOM.8DV1CP)	
	9.	2005-0051427A1	03/10/2005	Brauker, et al. (DEXCOM.019A)	
	10.	2005-0056552 A1	03/17/2005	Simpson, et al. (DEXCOM.020A)	
	11.	2005-0054909	03/10/2005	Petisce, et al. (DEXCOM.021A)	
	12.	2005-0051440	03/10/2005	Simpson, et al. (DEXCOM.022A)	
	13.	2005-0027180 A1	02/03/2005	Goode, et al. (DEXCOM.026A)	
	14.	2005-0027181 A1	02/03/2005	Goode, et al. (DEXCOM.025A)	
	15.	2005-0027463 A1	02/03/2005	Goode, et al. (DEXCOM.016A)	
	16.	5,190,041	03/02/1993	Palti	
	17.	5,343,869	09/06/1994	Pross, et al.	
	18.	5,469,846	11/28/1995	Khan	
	19.	5,484,404	01/16/1996	Schulman, et al.	
	20.	5,569,186	10/29/1996	Lord, et al.	
	21.	5,749,907	05/12/1998	Mann	
	22.	5,836,989	11/17/1998	Shelton	
	23.	5,904,708	05/18/1999	Goedeke	
	24.	5,995,860	11/30/1999	Sun, et al.	
	25.	6,122,536	09/19/2000	Sun, et al.	
	26.	6,135,978	10/24/2000	Houben, et al.	
	27.	6,175,752	01/16/2001	Say, et al.	
	28.	6,208,894	03/27/2001	Schulman, et al.	
	29.	6,248,067	06/19/2001	Causey, III, et al.	

Examiner Signature

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	10/789,359
	Filing Date	February 26, 2004
	First Named Inventor	Brauker, et al.
	Art Unit	3763
(Multiple sheets used when necessary)	Examiner	Mendez, Manuel A.
SHEET 2 OF 5	Attorney Docket No.	DEXCOM.037A

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number - Kind Code (if known) Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30.	6,272,480	08/07/2001	Tresp, et al.	
	31.	6,326,160	12/04/2001	Dunn, et al.	
	32.	6,475,750	11/05/2002	Han, et al.	
	33.	6,544,212	04/08/2003	Galley, et al.	
	34.	6,546,269	04/08/2003	Kurnik	
	35.	6,553,244	04/22/2003	Lesho, et al.	
	36.	6,558,321	05/06/2003	Burd, et al.	
	37.	6,558,351	05/06/2003	Steil et al.	
	38.	6,561,978	05/13/2003	Conn, et al.	
	39.	6,565,509	05/20/2003	Say, et al.	
	40.	6,572,545	06/03/2003	Knobbe, et al.	
	41.	6,575,905	06/10/2003	Knobbe, et al.	
	42.	6,633,772	10/14/2003	Ford, et al.	
	43.	6,648,821	11/18/2003	Lebel, et al.	
	44.	6,673,596	01/06/2004	Sayler, et al.	
	45.	6,694,191	02/17/2004	Starkweather, et al.	
	46.	6,731,976	05/04/2004	Penn, et al.	
	47.	6,740,075	05/25/2004	Lebel, et al.	
	48.	6,810,290	10/26/2004	Lebel, et al.	
	49.	6,813,519	11/02/2004	Lebel, et al.	
	50.	6,895,263	05/17/2005	Shin, et al.	
	51.	2003-0176183	09/18/2003	Drucker, et al.	
	52.	5,284,570	02/08/1994	Savage, et al.	
	53.	6,379,317	04/30/2002	Kintzig, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	54.	EP 0 098 592 A2	01/18/1984	Fujisawa Pharmaceutical Co., Ltd.		

Examiner Signature	Date Considered
--------------------	-----------------

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	10/789,359
	Filing Date	February 26, 2004
	First Named Inventor	Brauker, et al.
	Art Unit	3763
(Multiple sheets used when necessary)	Examiner	Mendez, Manuel A.
SHEET 3 OF 5	Attorney Docket No.	DEXCOM.037A

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.	Foreign Patent Document Country Code-Number-Kind Code Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T <sup>1</sup>
	55.	EP 0 534 074 A1	03/31/1993	Pfeiffer, Ernst F.		
	56.	EP 1 078 258 B1	02/28/2001	Kurnik, Ronald T.		
	57.	FR 2 760 962	09/25/1998	Klefsstad Sillonville Francis		
	58.	WO 90/00738	01/25/1990	Markwell Medical Institutes, Inc.		
	59.	WO 95/07109	03-16-1995	Ottawa Heart Institute Research Corporation		
	60.	WO 98/24358	06/11/1998	Enact Health Management Systems		
	61.	WO 99/48419	09/30/1999	Eglise, David		
	62.	WO 99/58973	11/18/1999	Cygnus, Inc.		
	63.	WO 00/19887	04/13/2000	Minimed Inc.		
	64.	WO 00/32098	06/08/2000	Health Hero Network, Inc.		
	65.	WO 00/33065	06/08/2000	Sayler, et al.		
	66.	WO 01/12158	02/22/2001	Thomas Jefferson University		
	67.	WO 01/52727 A1	07/26/2001	Minimed Inc.		
	68.	WO 01/58348 A2	08/16/2001	Minimed Inc.		
	69.	WO 01/88534 A2	11/22/2001	Cygnus, Inc.		
	70.	WO 02/24065 A1	03/28/2002	Knobbe, et al.		

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	71.	Abel, P. U.; von Woedtke, T. Biosensors for in vivo glucose measurement: can we cross the experimental stage. <i>Biosens Bioelectron</i> 2002, 17, 1059-1070	
	72.	Baker, et al. 1996. Dynamic delay and maximal dynamic error in continuous biosensors. <i>Anal Chem</i> , 68:1292-1297.	
	73.	Bani Amer, M. M. 2002. An accurate amperometric glucose sensor based glucometer with eliminated cross-sensitivity. <i>J Med Eng Technol</i> , 26(5):208-213.	
	74.	Bland, et al. 1990. A note on the use of the intraclass correlation coefficient in the evaluation of agreement between two methods of measurement. <i>Comput. Biol. Med.</i> , 20(5):337-340.	
	75.	Bode, et al. 1999. Continuous glucose monitoring used to adjust diabetes therapy improves glycosylated hemoglobin: A pilot study. <i>Diabetes Research and Clinical Practice</i> , 46:183-190.	
	76.	Bode, B. W. 2000. Clinical utility of the continuous glucose monitoring system. <i>Diabetes Technol Ther</i> , 2 Suppl 1, S35-41.	

Examiner Signature	Date Considered
<b>*Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	10/789,359
	Filing Date	February 26, 2004
	First Named Inventor	Brauker, et al.
	Art Unit	3763
(Multiple sheets used when necessary)	Examiner	Mendez, Manuel A.
SHEET 4 OF 5	Attorney Docket No.	DEXCOM.037A

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	77.	Bode, et al. 2000. Using the continuous glucose monitoring system to improve the management of type 1 diabetes. <i>Diabetes Technology &amp; Therapeutics</i> , 2 Suppl 1, S43-48.	
	78.	Bolinder, et al. 1992. Microdialysis measurement of the absolute glucose concentration in subcutaneous adipose tissue allowing glucose monitoring in diabetic patients. <i>Diabetologia</i> , 35:1177-1180.	
	79.	Bremer, et al. 1999. Is blood glucose predictable from previous values? A solicitation for data. <i>Diabetes</i> , 48:445-451.	
	80.	Chia, C. W.; Saudek, C. D. Glucose sensors: toward closed loop insulin delivery. <i>Endocrinol Metab Clin North Am</i> 2004, 33, 175-95, xi	
	81.	Choleau, et al. 2002. Calibration of a subcutaneous amperometric glucose sensor implanted for 7 days in diabetic patients. Part 2. Superiority of the one-point calibration method. <i>Biosensors and Bioelectronics</i> , 17:647-654.	
	82.	Garg, S.; Schwartz, S.; Edelman, S. Improved Glucose Excursions Using an Implantable Real-Time Continuous Glucose Sensor in Adults with Type I Diabetes. <i>Diabetes Care</i> 2004, 27, 734-738	
	83.	Gilligan, B. C.; Shults, M.; Rhodes, R. K.; Jacobs, P. G.; Brauker, J. H.; Pintar, T. J.; Updike, S. J. Feasibility of continuo long-term glucose monitoring from a subcutaneous glucose sensor in humans. <i>Diabetes Technol Ther</i> 2004, 6, 378-386	
	84.	Heller, A. Implanted electrochemical glucose sensors for the management of diabetes. <i>Annu Rev Biomed Eng</i> 1999, 1, 153-175	
	85.	Hunter, I., Jones, L., Kanigan, T., Brennan, C., Sanbol, L. Sosnowski, L. Minimally Invasive Glucose Sensor and Insulin Delivery System. MIT Home Automation and Healthcare Consortium 2000.	
	86.	Kerner, W. 2001. Implantable glucose sensors: Present status and future developments. <i>Exp. Clin. Endocrinol. Diabetes</i> , 109 Suppl 2, S341-346.	
	87.	Lerner, et al. 1984. An implantable electrochemical glucose sensor. <i>Ann. N. Y. Acad. Sci.</i> , 428:263-278.	
	88.	Lynch, et al. 2001. Estimation-based model predictive control of blood glucose in type I diabetics: A simulation study. <i>Proceedings of the IEEE 27th Annual Northeast Bioengineering Conference</i> , pp. 79-80.	
	89.	March, W. F. Dealing with the delay. <i>Diabetes Technol Ther</i> 2002, 4, 49-50	
	90.	Martin, R. F. 2000. General Deming regression for estimating systematic bias and its confidence interval in method-comparison studies. <i>Clinical Chemistry</i> , 46(1):100-104.	
	91.	Monsod, et al. 2002. Do sensor glucose levels accurately predict plasma glucose concentrations during hypoglycemia and hyperinsulinemia? <i>Diabetes Care</i> , 25(5):889-893.	
	92.	Sansen, et al. 1985. "Glucose sensor with telemetry system." In Ko, W. H. (Ed.). <i>Implantable Sensors for Closed Loop Prosthetic Systems</i> . Chap. 12, pp. 167-175, Mount Kisco, NY: Futura Publishing Co.	
	93.	Selam, J. L. Management of diabetes with glucose sensors and implantable insulin pumps. From the dream of the 60s to the realities of the 90s. <i>ASAIO J</i> 1997, 43, 137-142	
	94.	Shichiri, M.; Kawamori, R.; Yamasaki, Y.; Hakui, N.; Abe, H. Wearable artificial endocrine pancreas with needle-type glucose sensor. <i>Lancet</i> 1982, 2, 1129-1131	
	95.	Shichiri, et al. 1986. Telemetry glucose monitoring device with needle-type glucose sensor: A useful tool for blood glucose monitoring in diabetic individuals. <i>Diabetes Care</i> , 9(3):298-301.	

Examiner Signature	Date Considered
<b>*Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>	Application No.	10/789,359
	Filing Date	February 26, 2004
	First Named Inventor	Brauker, et al.
	Art Unit	3763
(Multiple sheets used when necessary)	Examiner	Mendez, Manuel A.
SHEET 5 OF 5	Attorney Docket No.	DEXCOM.037A

### NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>1</sup>
	96.	Shichiri, M.; Kawamori, R.; Yamasaki, Y.; Hakui, N.; Asakawa, N.; Abe, H. Needle-type Glucose Sensor for Wearable Artificial Endocrine Pancreas. Book Implantable Sensors 1985, 197-210	
	97.	Sternberg, et al. 1996. Does fall in tissue glucose precede fall in blood glucose? <i>Diabetologia</i> , 39:609-612.	
	98.	Tilbury, et al. 2000. Receiver operating characteristic analysis for intelligent medical systems--A new approach for finding confidence intervals. <i>IEEE Transactions on Biomedical Engineering</i> , 47(7):952-963.	
	99.	Trajanoski, et al. 1998. Neural predictive controller for insulin delivery using the subcutaneous route. <i>IEEE Transactions on Biomedical Engineering</i> , 45(9):1122-1134.	
	100	Wilkins, et al. 1995. Integrated implantable device for long-term glucose monitoring. <i>Biosens. Bioelectron.</i> , 10:485-494.	
	101	Wientjes, K. J. C. Development of a glucose sensor for diabetic patients. 2000	
	102	Wilkins, E.; Atanasov, P. Glucose monitoring: state of the art and future possibilities. <i>Med Eng Phys</i> 1995, 18, 273-288	
	103	Wilson, et al. 1992. Progress toward the development of an implantable sensor for glucose. <i>Clin. Chem.</i> , 38(9):1613-1617.	
	104	U.S. Patent Application No. 09/447,227, filed 11/22/99, Docket No. DEXCOM.008DV1. (See Image File Wrapper)	
	105	U.S. Patent Application No. 10/838,658 filed 05/03/04, Docket No. DEXCOM.045A. (See Image File Wrapper)	
	106	U.S. Patent Application No. 10/838,909 filed 05/03/04, Docket No. DEXCOM.044A. (See Image File Wrapper)	
	107	U.S. Patent Application No. 10/838,912 filed 05/03/04, Docket No. DEXCOM.043A. (See Image File Wrapper)	
	108	U.S. Patent Application No. 10/885,476 filed 07/06/04, Docket No. DEXCOM.048A. (See Image File Wrapper)	
	109	U.S. Patent Application No. 10/896,312 filed 07/21/04, Docket No. DEXCOM.023A. (See Image File Wrapper)	

1972259  
100505

Examiner Signature	Date Considered
<b>*Examiner:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.